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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,888

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Daniel G. Dadourian

DADO-001

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,888

Applicant(s)

DADOURIAN, DANIEL G.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 16-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-1-2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, drawn to an apparatus for locating an interventional device relative to the ostium of a branch vessel, classified in class 606, subclass 191.
 - II. Claim 16-22, drawn to a method of locating an interventional device relative to the ostium of a branch vessel, classified in class 623, subclass 1.11.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to as a stent delivery device or for example as an internal pressure applier. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
3. During a telephone conversation with William English on 9 August 2006 a provisional election was made without traverse to prosecute the invention of an

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apparatus for locating an interventional device relative to the ostium of a branch vessel, claims 1-15. Affirmation of this election must be made by applicant when replying to this Office action. Claims 16-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because they are drawn by hand. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 7, 8, 9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ensminger et al. (US Patent 5,256,146).**

Ensminger'146 discloses a vascular catheterization system containing a sheath (12) having a proximal (towards element 18) and a distal (towards element 22) ends

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which is capable of being affixed to an interventional device, and an ostial locator wire (14) that is slidably disposed within sheath (12) (see progression between Figure 1 and 2), the ostial locator wire (14) assumes an expanded configuration (Figure 2) when it is extended from the distal end of the sheath (Figure 2, see Figure 1 for unexpanded configuration). Furthermore, the device taught by Ensminger'146 is capable of partially encircling an interventional device.

7. Regarding Claim 7, the expanded configuration of the ostial locator wire (14) is the diameter of the main vessel shown (Figure 2), since the ostial vessel will have a smaller diameter than the main vessel, and the ostial locator wire must be able to fit through the main vessel to reach the ostial vessel, therefore, the ostial wire is larger than the diameter of the ostial vessel (column 3, lines 50-53).

8. Regarding Claim 8 and 12, the expanded configuration of the ostial locator wire is a spiral shape (Figure 2) capable of encircling a stent because of its size and the offset axis of the expanded portion.

9. Regarding Claim 9, the expanded configuration defines a portion of a disk (Figure 2).

10. Regarding Claim 11, the final loop in the helix-shaped ostial locator wire (14) can serve as a lasso that is capable of retaining the expanded configuration centered on an interventional device.

11. Regarding Claim 13, the helix-shaped loop will flatten out after being pressed into contact with the tissue surrounding an ostium because Ensminger'146 discloses that

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the ostial locator wire (14) is made out of resilient material (column 34-39), which will elastically deform under force.

12. Regarding Claim 14, the distal most turn of the helix-shaped loop is substantially the same diameter of the vessel, since the interventional device/stent is being used to put pressure on the walls of the vessel, the diameter of the distal most turn of the helix-shaped loop will be the same diameter of the interventional device/stent.

13. Claims 1, 10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kupiecki et al. (US Patent 5,669,931).

14. Regarding Claim 1, Kupiecki'931 discloses an occlusive implant containing a sheath (4b) having a proximal (towards number 70 in Figure 6) and a distal end (towards element 4b), which is capable of being affixed to an interventional device, and an ostial locator wire (20) having a collapsed configuration (Figure 2a) and an expanded configuration (Figure 3) when it is expanded from the distal end of the sheath (4b) (see Figure 6). Furthermore, the device taught by Kupiecki'931 is capable of partially encircling an interventional device (see offset axis of expanded portion in Figure 2).

15. Regarding Claim 10, Kupiecki'931 teaches an atraumatic tip (32) on the ostial locator wire (20) (column 6, lines 18-26).

16. Regarding Claim 15, Kupiecki'931 teaches that the ostial locator wire (20) contains radiopaque portions (column 6, lines 27-33).

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Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ensminger'146, as applied to Claim 1, in further view of McGuckin, et al. (US Patent 6,589,214).

19. Ensminger'146 teaches the limitations of Claim 2, except for the use of a fastener.

20. Regarding Claim 2, McGuckin'214 teaches an introducer sheath containing a fastener (40) that can be used to attach an interventional device to a sheath (21).

Regarding Claim 3, the fastener (40) comprises a thin flexible sheet that can wrap around an interventional device. Regarding Claim 4 and 5, the fastener contains a clasp (85) (column 6, lines 21-28), which is friction fit into engagement with the fastener (40) so the fastener can retain an interventional device (column 6, lines 21-28). Regarding

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Claim 6, the clasp (85) is adapted to be fit to an interventional device using a biocompatible adhesive. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a fastener to make sure that the sheath and an interventional device are securely fastened to each other and not lost in the patient's body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lmb

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER